FOI 23/788

Dear

Thank you for your FOI request dated 17th October 2023.

> *"I wish to know under the 'freedom of information' how many reported cases of the following side effects from Salazopyin (Sulfasalazine) have been reported to yellow-card-sceme? Since introduction to the market the following side-effects have been reported: 1 Inflammation of the lining of the brain 2 Severe diarrhoea 3 Other blood disorders including anaemia, enlarged glands (lymph nodes) 4 Blood vessel inflammation 5 Loss of appetite 6 Hallucinations 7 Changes in mental state 8 Changes in smell 9 Inflammation of the sac surrounding the heart (pericarditis) 10 Inflammation of the heart muscle (myocarditis) 11 Bluish tint to skin due to poor circulation 12 Lung complications with breathlessness 13 Inflammation of the salivary glands on either side of the face 14 Kidney inflammation and kidney pain, 15 Liver disease (hepatitis) 16 Yellowing of the skin or whites of the eyes (jaundice) 17 Inflammation of pancreas, which causes severe pain in the 18 abdomen and face 19 Rash, reddening or blistering of the skin, eczema, swelling of the skin 20 Tingling, numbness, pain in hands and feet 21 Blood and crystals in urine 22 Urine or motions may become a yellow/orange colour which is normal and harmless. (See section 6 General Advice for further information) 21 Temporary infertility in men. Fertility returns when treatment is stopped. Normal contraception should still be used 22 Dryness of the mouth and eyes These have been listed in the manufacturers patients leaflet I am particularly interested in the following numbered items 1/3/4/9/10/12/14/15/17/20. These have been listed as reported since introduction to market without any qualifying figures so the public are unable to see the potential for harm if prescribed. If you have any information on these side effects I would like some help with this."*

We can confirm that the MHRA does hold the requested information and it can be accessed using the link below:

https://info.mhra.gov.uk/drug-analysis-profiles/dap.html?drug=./UK_EXTERNAL/NONCOMBINED/UK_NON_001048901411.zip&agency=MHRA

For suspected side effects being reported for medicines, the MHRA publishes this information in the form of interactive Drug Analysis Profiles (iDAPs). Each iDAP contains a complete listing of all suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme. This includes all reports received

from healthcare professionals, members of the public, and pharmaceutical companies. It is important to note that reported adverse reactions have not been proven to be related to the drug, and should not be interpreted as a list of known side effects.

I hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Kind regards,

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